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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,851	11/20/2001	Rachel E. Meyers	10147-56U1	1565

7590 10/06/2003

Intellectual Property Group
MILLENNIUM PHARMACEUTICALS, INC.
75 Sidney Street
Cambridge, MA 02139

EXAMINER	
SCHULTZ, JAMES	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,851	MEYERS ET AL.	
	Examiner	Art Unit	
	J. Douglas Schultz	1635	

-- Th MAILING DATE of this communication appears on the cover sh et with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 8, and 24-26 (each in part), drawn to a method of modulating the ability of a cell to affect the glycosylation state of a target the method comprising modulating the activity of an enzyme consisting of the 47169 protein in the cell wherein activity is inhibited by inhibiting expression by administering to the cell an antisense oligonucleotide that hybridizes under stringent conditions with a polynucleotide having the nucleotide sequence SEQ ID NO: 1, classified in class 514, subclass 44, for example.

II. Claims 1-5, 7, 8, and 24-26 (each in part), drawn to a method of modulating the ability of a cell to affect the glycosylation state of a target the method comprising modulating the activity of an enzyme consisting of the 47169 protein in the cell wherein activity is inhibited by inhibiting expression by administering to the cell an antisense oligonucleotide that hybridizes under stringent conditions with a polynucleotide having the nucleotide sequence SEQ ID NO: 3, classified in class 514, subclass 44, for example.

III. Claims 1, 9, 10, and 24-26 (each in part), drawn to a method of modulating the ability of a cell to affect the glycosylation state of a target the method comprising modulating the activity of an enzyme consisting of the 47169 protein in the cell wherein activity is inhibited by administering to the cell an antibody, classified in class 424, subclass 130.1, for example.

IV. Claims 1, 11, 12, and 24-26 (each in part), drawn to a method of modulating the ability of a cell to affect the glycosylation state of a target the method comprising modulating the activity of an enzyme consisting of the 47169 protein in the cell wherein activity is enhanced by administering to the cell an expression vector encoding 47169 protein, classified in class 514, subclass 44, for example.

V. Claims 1, 13-17, 19, and 24-26 (each in part), drawn to a method of modulating the ability of a cell to affect the glycosylation state of a target the method comprising modulating the activity of an enzyme consisting of the 33935 protein in the cell wherein activity is inhibited by inhibiting expression by administering to the cell an antisense oligonucleotide that hybridizes under stringent conditions with a polynucleotide having the nucleotide sequence SEQ ID NO: 11, classified in class 514, subclass 44, for example.

VI. Claims 1, 13-16, 18, 19, and 24-26 (each in part), drawn to a method of modulating the ability of a cell to affect the glycosylation state of a target the method comprising modulating the activity of an enzyme consisting of the 33935 protein in the cell wherein activity is inhibited by inhibiting expression by administering to the cell an antisense oligonucleotide that hybridizes under stringent conditions with a polynucleotide having the nucleotide sequence SEQ ID NO: 13, classified in class 514, subclass 44, for example.

VII. Claims 1, 20, 21, and 24-26 (each in part), drawn to a method of modulating the ability of a cell to affect the glycosylation state of a target the method comprising modulating the activity of an enzyme consisting of the 33935 protein in the cell

wherein activity is inhibited by administering to the cell an antibody, classified in class 424, subclass 130.1, for example.

VIII. Claims 1, 22, and 23-26 (each in part), drawn to a method of modulating the ability of a cell to affect the glycosylation state of a target the method comprising modulating the activity of an enzyme consisting of the 33935 protein in the cell wherein activity is enhanced by administering to the cell an expression vector encoding 33935 protein, classified in class 514, subclass 44, for example.

IX. Claims 27-31 and 34-35 (each in part), drawn to a method for assessing whether a test compound is useful for modulating a phenomenon comprising adding the test compound to a first composition comprising SEQ ID NO: 2, classified in class 435, subclass 6, for example.

X. Claims 27-31 and 34-35 (each in part), drawn to a method for assessing whether a test compound is useful for modulating a phenomenon comprising adding the test compound to a first composition comprising SEQ ID NO: 12, classified in class 435, subclass 6, for example.

XI. Claim 32, drawn to a method of making a pharmaceutical composition, classification dependent upon compound structure.

XII. Claim 33, drawn to a method of modulating in human a phenomenon comprising administering a pharmaceutical composition, classification dependent upon compound structure.

XIII. Claim 34 (in part), drawn to a method for identifying a compound is useful for modulating a phenomenon comprising contacting the test compound and a

polypeptide, or with a cell that expresses the polynucleotide wherein the polypeptide is encoded by a nucleic acid molecule comprising a portion having a nucleotide sequence which is at least 90% identical to SEQ ID NO: 1, classified in class 435, subclass 6, for example.

XIV. Claim 34 (in part), drawn to a method for identifying a compound is useful for modulating a phenomenon comprising contacting the test compound and a polypeptide, or with a cell that expresses the polynucleotide wherein the polypeptide is encoded by a nucleic acid molecule comprising a portion having a nucleotide sequence which is at least 90% identical to SEQ ID NO: 3, classified in class 435, subclass 6, for example.

XV. Claim 34 (in part), drawn to a method for identifying a compound is useful for modulating a phenomenon comprising contacting the test compound and a polypeptide, or with a cell that expresses the polynucleotide wherein the polypeptide is encoded by a nucleic acid molecule comprising a portion having a nucleotide sequence which is at least 90% identical to SEQ ID NO: 11, classified in class 435, subclass 6, for example.

XVI. Claim 34 (in part), drawn to a method for identifying a compound is useful for modulating a phenomenon comprising contacting the test compound and a polypeptide, or with a cell that expresses the polynucleotide wherein the polypeptide is encoded by a nucleic acid molecule comprising a portion having a nucleotide sequence which is at least 90% identical to SEQ ID NO: 13, classified in class 435, subclass 6, for example.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I, II, III, IV, V, VI, VII, VIII, IX, X, XI, XII, XIII, XIV, XV, and XVI are directed to methods that are distinct both physically and functionally, and are not required one for the other.

Invention I requires search and consideration of an antisense molecule that hybridizes to SEQ ID NO: 1, which is not required by any of the other Inventions. Invention II requires search and consideration of an antisense molecule that hybridizes to SEQ ID NO: 3, which is not required by any of the other Inventions. Invention III requires search and consideration of inhibiting 47169 protein activity using an antibody, which is not required by any of the other Inventions. Invention IV requires search and consideration of enhancing 47169 protein activity using an expression vector, which is not required by any of the other Inventions.

Invention V requires search and consideration of an antisense molecule that hybridizes to SEQ ID NO: 11, which is not required by any of the other Inventions. Invention VI requires search and consideration of an antisense molecule that hybridizes to SEQ ID NO: 13, which is not required by any of the other Inventions. Invention VII requires search and consideration of inhibiting 33935 protein activity using an antibody, which is not required by any of the other Inventions. Invention VIII requires search and consideration of enhancing 33935 protein activity using an expression vector, which is not required by any of the other Inventions.

Invention IX requires search and consideration of SEQ ID NO: 2, which is not required by any of the other Inventions. Invention X requires search and consideration of SEQ ID NO: 12, which is not required by any of the other Inventions.

Invention XI requires search and consideration of making a pharmaceutical composition, which is not required by any of the other Inventions. Invention XII requires search and consideration of administering a pharmaceutical composition to a human subject, which is not required by any of the other Inventions.

Invention XIII requires search and consideration of a method for identifying a compound useful for modulating a phenomenon using SEQ ID NO: 1, which is not required by any of the other Inventions. Invention XIV requires search and consideration of a method for identifying a compound useful for modulating a phenomenon using SEQ ID NO: 3, which is not required by any of the other Inventions. Invention XV requires search and consideration of a method for identifying a compound useful for modulating a phenomenon using SEQ ID NO: 11, which is not required by any of the other Inventions. Invention XVI requires search and consideration of a method for identifying a compound useful for modulating a phenomenon using SEQ ID NO: 13, which is not required by any of the other Inventions.

This application contains claims directed to the following patentably distinct species of the claimed invention:

a. Non-covalent binding between a protein and one of a cell

b. Non-covalent binding between a protein and one of a virus

c. Non-covalent binding between a protein and one of another protein

d. Cell signaling

e. Cell differentiation

f. Tumorigenesis

g. Cell adhesion

h. Cell motility

i. Cell-to-cell interaction

j. Cell invasivity

k. Cell proliferation

l. Gene transcription

m. An immune response

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 27, 31, 32, 33, and 34 are generic.

If applicant selects any one of Inventions IX, X, XI, XII, XIII, XIV, XV, or XVI, one species from the phenomenon group must be chosen to be fully responsive.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD

Karen A. Lacourciere

KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER